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ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/886,779	SABANAYAGAM ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments

1. Applicant's response to the office action filed on July 10, 2007 has been entered. The claims pending in this application are claims 11 and 23-38. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on July 10, 2007.

Claim Objections

2. Claim 11 is objected to because of the following informality: "a unique" in preamble and (d) should be "an unique".

3. Claim 23 is objected to because of the following informality: "a unique" in d) should be "an unique".

4. Claims 24-29, 34, and 35 are objected to because of the following informality: "the sequence of interest" should be "the unique sequence of interest".

5. Claims 24-26, 32, and 33 are objected to because of the following informality: "a same" should be "the same".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. New Matter

Claims 11, 23-29, 34, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "multiple copies of a sequence of interest extending in the array's z dimension, wherein each copy has an identical genetic oligonucleotide that is attached to the array's x and y coordinates and wherein each copy also carries a unique nucleotide of interest repeated at least two times in the z dimension of the array" is added to the newly amended independent claim 11 and can be read as multiple copies of a sequence of interest extending in the array's z dimension wherein each copy has an identical genetic oligonucleotide that is attached to the array's x and y coordinates and the identical genetic oligonucleotide extends along either x or y dimension and wherein each copy also carries a unique nucleotide of interest repeated at least two times in the z dimension of the array. The limitation "multiple copies of a sequence of interest extending in the array's z dimension, wherein each copy has different unique sequence attached to the array's x and y coordinates, each different sequence being complementary to the sequence of interest, wherein at least two copies of the different unique sequence are repeated along the z-dimension of the array" is added to the newly amended independent claim 23 and can be read as multiple copies of a sequence of interest extending in the array's z dimension wherein each copy has different unique sequence attached to the array's x and y coordinates and the different unique sequence extends along either x or y dimension,

each different sequence of the sequence of interest is complementary to the sequence of interest and wherein at least two copies of the different unique sequence are repeated along the z-dimension of the array. Although original filed claim 1 describes that a solid support comprising a plurality of positions for oligonucleotides, said positions defined by x and y coordinates and a plurality of identical oligonucleotides, each oligonucleotide comprising a sequence, nowhere in the page 10, lines 15-18 and page 11, lines 19-23 of the specification suggested by applicant and other parts of the specification describe multiple copies of a sequence of interest extending in the array's z dimension wherein each copy has an identical genetic oligonucleotide that is attached to the array's x and y coordinates and the identical genetic oligonucleotide extends along either x or y dimension and wherein each copy also carries a unique nucleotide of interest repeated at least two times in the z dimension of the array as recited in claim 11 and multiple copies of a sequence of interest extending in the array's z dimension wherein each copy has different unique sequence attached to the array's x and y coordinates and the different unique sequence extends along either x or y dimension, each different sequence of the sequence of interest is complementary to the sequence of interest and wherein at least two copies of the different unique sequence are repeated along the z-dimension of the array as recited in claim 23.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application". MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE

WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 11, 23-29, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 11 recites the limitation "the target sequence" in (d) of the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase "target sequence" before "the target sequence". Please clarify.

11. Claim 11 or 23 is rejected as vague and indefinite because it is unclear that what sequence in a target sequence can be considered as an unique portion corresponding to an unique sequence of interest of a circular DNA. Please clarify.

12. Claim 11 is rejected as vague and indefinite in view of the preamble of the claim. Since the preamble of the claim requires that between each unique sequence of the interest there is at least one region that is complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates and the identical generic oligonucleotide extends along either x or y dimension, if at least one region that is fully complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates and the identical generic oligonucleotide is attached to the array's x and y coordinates by a chemical bond, multiple copies of a sequence interest extend along either

x or y dimension and does not extend along z dimension which is opposite to the claim. Please clarify.

13. Claim 23 is rejected as vague and indefinite in view of the preamble of the claim. Since the preamble of the claim requires each copy of a sequence of interest contains a different unique sequence and each different sequence is complementary to the sequence of interest, it is unclear how the different unique sequence of the sequence of interest can be complementary to the sequence of interest as recited in the claim. Please clarify.

14. Claim 23 is rejected as vague and indefinite in view of d) of the claim because it is unclear whether 3' terminus is from a circular DNA or not. Please clarify.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 30-33 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.,* (US Patent No. 5,753,439, filed on May 19, 2003).

Smith et al., teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine

or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about 10,000 different probes (see column 9, lines 18-34). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1 and 2).

Regarding claim 30, claim 30 is directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate wherein the at least two copies of sequence of interest are separated by at least one generic nucleic acid sequence and each sequence of interest is different in each extended immobilized oligonucleotide. Since Smith *et al.,* teach an array comprising 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34 and column 15, claims 1 and 2) and claim 30 does not require that the sequence of interest is different from the generic nucleic acid sequence, Smith *et al.*, teach an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., some repeats from 2000 repeats) wherein the at least two copies of sequence of interest (ie., some repeats from 2000 repeats) are separated by at least one generic nucleic acid sequence (ie., other repeats from 2000 repeats) and each sequence of interest is different in each extended immobilized oligonucleotide. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since

each of these probes from one end to another end has 5' to 3' direction and the array itself is a three dimension structure. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding 31-33, since these different probes taught by Smith *et al.*, have 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), Smith *et al.*, disclose that each extended immobilized oligonucleotide comprises at least three copies of said sequence of interest (ie., three repeats from 2000 repeats) separated by at least two copies of a generic nucleic acid sequence (ie., other two repeats from 2000 repeats) as recited in claim 31 and each extended immobilized oligonucleotide comprises at least 10 to 50 copies of said sequence of interest (ie., 10-50 repeats from 2000 repeats) separated by the same generic nucleic acid sequence (ie., other identical repeats from 2000 repeats) as recited in claim 32 and 33.

Regarding claims 36-38, different probes on the arrays in Figures 6A to 6C taught by Smith *et al.*, have 10-109 repeats wherein 5' and 3' ends of these probes are labeled with biotin and rhodamine respectively. Target nucleic acids comprising 88, 55, and 17 repeats with a fluorescein at their 3' ends are hybridized with an identical array in separate experiments and digested with S1 nuclease. Then strand displacement assays are performed. When the probe contains more internal repeats than the target, the rhodamine label is lost in the strand displacement and the resultant product is red. Similarly, when the target contains more internal repeats than the probe, the fluorescein label is lost and the product is green. When the probe and the target both contain the same number of repeats, both rhodamine and fluorescein remain and the resultant color is yellow (see column 12, example 4, and Figures 6A to 6C). When target nucleic acids comprising 88, 55, and 17 repeats hybridize with their corresponding probes

(having 88, 55, and 17 repeats) on the array, the resultant colors must be yellow. Therefore, Smith *et al.*, teach that at least two copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 36, at least ten copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 37, and at least fifty copies of a fragment of a template nucleic acid (ie., 88 or 55 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeat of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 38.

Therefore, Smith *et al.*, teach all limitations recited in claims 30-33 and 36-38.

Response to Arguments

In page 9, last paragraph bridging to page 11, first paragraph of applicant's remarks, applicant argues that: (1) "[A]pplicants submit that the product of the present invention differs from the product of Smith in that the oligonucleotide probes in the arrays of the present invention have been extended at their 3' termini thus resulting in differing 3' termini according to the sequence of interest. The **3' terminus** of each strand of the **Smith array** is always the same. The array of Smith comprises oligonucleotide probes that 'comprise: 5'-region arid 3' regions which are complementary to portions of the nucleic acid and an internal variable region' (col. 7, lines 3-

5). Even if this variable region comprises multiple repeats of a same target sequence, the middle part of the probe is always flanked by the 3' and 5' sequences that do not belong to the target sequence. This means that each probe has 100% identical 5' ends and 100% identical 3' ends, and a variable region in between. This is not the same with the claimed arrays"; and (2) "[I]n claim 32, the probes are similarly homogenous towards the z dimensional, i.e. the 3' end of the probe, The difference being that the 5' end of the each of the probe comprises a sequence that is unique and when a circular template that has a sequence complementary to at least a portion of the unique sequence attaches to the unique original probe, an array will be created that again has a repeat with unique sequence followed by a second region, followed by a second copy of the unique sequence and so forth. Again, unlike in the probes on the arrays of Smith, there will be no separate region at the end of the variable region of each probe, and therefore the 3' end of each probe is unique".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the claims do not require that the 3' terminus of each extended immobilized oligonucleotide is the same as argued by applicant. Second, the claims do not require that separate region is at the end of the variable region of each probe and the 3' end of each probe is unique as argued by applicant.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. No claim is allowed.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

September 13, 2007

FRANK LU
PRIMARY EXAMINER